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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,823	03/18/2004	Shiv Srivastava	4995.0053-01	5907

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EXAMINER	
RAWLINGS, STEPHEN L	
ART UNIT	PAPER NUMBER
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/802,823	SRIVASTAVA ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2004 and 28 October 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-11 and 18-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *6-11 and 18-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed March 18, 2004, is acknowledged and has been entered. Claims 1-4 and 12-17 have been canceled. Claims 5-8 have been amended. Claims 18-35 have been added.

2. The amendment filed October 28, 2004, is acknowledged and has been entered. Claim 5 has been canceled. Claims 18-21, 28-30, and 32-34 have been amended.

3. Claims 6-11 and 18-35 are pending in the application and are currently subject to restriction.

Election/Restrictions

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 6-11 and 32-35, drawn to a method for detecting prostate cancer, classified, for example, in class 435, subclass 6.

Group II. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 4, classified, for example, in class 536, subclass 23.1.

Group III. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 6, classified, for example, in class 536, subclass 23.1.

Group IV. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 7, classified, for example, in class 536, subclass 23.1.

Group V. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 9, classified, for example, in class 536, subclass 23.1.

Group VI. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 10, classified, for example, in class 536, subclass 23.1.

Group VII. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 11, classified, for example, in class 536, subclass 23.1.

Group VIII. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 12, classified, for example, in class 536, subclass 23.1.

Group IX. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 13, classified, for example, in class 536, subclass 23.1.

Group X. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 14, classified, for example, in class 536, subclass 23.1.

Group XI. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 15, classified, for example, in class 536, subclass 23.1.

Group XII. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 16, classified, for example, in class 536, subclass 23.1.

Group XIII. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 17, classified, for example, in class 536, subclass 23.1.

Group XIV. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 18, classified, for example, in class 536, subclass 23.1.

Group XV. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 19, classified, for example, in class 536, subclass 23.1.

Group XVI. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 20, classified, for example, in class 536, subclass 23.1.

Group XVII. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 21, classified, for example, in class 536, subclass 23.1.

Group XVIII. Claim 18, insofar as the claim is drawn to the nucleic acid of SEQ ID NO: 22, classified, for example, in class 536, subclass 23.1.

Group XIX. Claims 20 and 21, drawn to a nucleic acid comprising at least 30 contiguous nucleotides of SEQ ID NO: 1, classified, for example, in class 536, subclass 23.1.

Group XX. Claims 22-31, insofar as the claim is drawn to a method of detecting a PCGEM1 nucleic acid in a biological sample, classified, for example, in class 435, subclass 6.

5. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups II-XIX are products, whereas the inventions of Groups I and XX are processes.

The inventions of Groups II-XIX and the inventions of Groups I and XX are unrelated because the products of Groups II-XIX are not specifically used or otherwise involved in the processes of Groups I and XX.

The inventions of Groups II-XIX are patentably distinct, each from the others, because each is a nucleic acid molecule consisting of, or comprising a distinct polynucleotide sequence.

Because of such differences, the search necessary to examine claims directed to any of the inventions of Groups II-XIX is not the same, nor is it coextensive with the search necessary to examine claims directed to any of the others. Accordingly, a separate and different search would have to be performed to examine claims directed to any one of these groups of inventions. Therefore, the examination of more than one of the inventions would constitute a serious burden.

Since the inventions of Groups II-XIX are patentably distinct, each from the others, and because the examination of more than one could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

If not unrelated, the inventions of Groups I and IV are patentably distinct for the following reasons:

The inventions of Group I are processes for detecting prostate cancer, whereas the inventions of Group IV are processes for detecting a nucleic acid molecule in a biological sample; therefore, the inventions of Groups I and IV have different purposes or objectives.

In addition, because the inventions have such different purposes or objectives, the different processes necessarily comprise different process steps. For example, these different processes may involve the acquisition of different samples from different sources (e.g., different populations of subjects or patients), as well as the measurement of different endpoints, and the establishment of different correlations between those endpoints. Moreover, the processes of the inventions of Group I necessarily involve the acquisition of a biological sample, and the correlation of a measured endpoint and the presence in the subject from which the sample was acquired of prostate cancer cells, whereas the processes of the inventions of Group IV do not. Furthermore, because the inventions of the different groups have different purposes or objectives, and involve the measurement of different endpoints and the establishment of different correlations, they necessarily have different criteria for success. For these reasons, the inventions of Groups I and IV are patentably distinct.

Because the inventions of Groups I and IV are distinct for these reasons, the search required to examine claims directed to any one of these inventions is not the same, nor is it coextensive with the search required to examine claims directed to any other. Furthermore, the inventions of Groups I and IV have acquired a separate status in the art, as evidenced by their art-recognized divergence in subject matter. Because different searches would have to be performed to examine claims directed to the inventions of Groups I and IV, an examination of both would constitute a serious burden.

Since the inventions of Groups I and IV have been shown to be patentably distinct, and because the examination of both could not be made without serious burden, it is proper to restrict each from the other. See MPEP § 803.

6. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, searching more than one invention encompassed by the claim would constitute a serious burden; therefore, restriction for examination purposes as indicated is proper.

7. This application contains claims 6-11 and 32-35 directed to patentably distinct species of the invention of Group I, wherein said nucleic acid is amplified with at least two nucleotide sequences selected from the group consisting of SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13, SEQ ID NO: 14, SEQ ID NO: 15, SEQ ID NO: 16, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 20, SEQ ID NO: 21, and SEQ ID NO: 22.

Each species of the invention of Group I is patentably distinct from the others since is a materially different process comprising amplifying a nucleic acid using at least two nucleotide sequences of a group of distinct nucleotide sequences.

Accordingly, the examination of claims directed to any one species of invention would require a unique search that is not required for examination of any of the other species of invention, and the search of any one species will not provide adequate information regarding any other. Moreover, the search necessary to examine claims directed to any one species of invention is not the same, nor is it coextensive with the search necessary to examine claims directed to any other. Since having to perform more than one search would constitute a serious burden, it is proper to restrict these species of invention and require Applicant to elect only one. See MPEP § 809.

Applicant is required under 35 U.S.C. 121 to specifically elect a single species of invention by identifying the two or more nucleotide sequences to which the claims of elected group of inventions will be directed during prosecution on the merits, and to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that novelty and nonobviousness of the elected species of invention would render claims directed to

that species allowable over the prior art, but not necessarily over the requirements set forth under 35 U.S.C. §§ 101 and 112.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species, which are written in dependent form, or otherwise, include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D., whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Primary Examiner
Art Unit 1643

slr
January 8, 2007